

REMARKS

By this Amendment, Applicant proposes amending claims 47 and 50, and canceling claims 44, 45, 52, and 58 without prejudice or disclaimer of the subject matter contained therein. Accordingly, claims 40-43, 46-51, 53-56, and 59-62 will be pending in this application upon entry of the proposed amendments. The amendments are fully supported by the application as originally filed, and no new matter has been introduced by this Amendment.

In the final Office Action mailed July 3, 2008, claims 40-56 and 58-62 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,901,288 to Janke et al. ("*Janke*"); claims 47-53 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of *Janke* in view of the claims of U.S. Patent No. 6,408,213 to Bartig et al. ("*Bartig*") or U.S. Patent No. 6,192,280 to Sommer et al. ("*Sommer*"); claims 47, 48, 51, and 52 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,714,823 to De Lurgio et al. ("*De Lurgio*"); claims 47-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *De Lurgio* in view of *Bartig* or *Sommer*; and claims 61 and 62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *De Lurgio*; and claims 54-56 and 58-60 were allowed. Applicant gratefully acknowledges the indication of allowable subject matter.

Applicant proposes amending claim 50 to correct a typographical error.

I. Double Patenting Rejection

Applicant traverses the double patenting rejections of claims 40-43, 46-56, and 59-62 because claims 40-43, 46-56, and 59-62 patentably distinguish over the claims of *Janke*, alone or in combination with *Bartig* or *Sommer*. For the sole purpose of advancing prosecution, however, and without acceding to the grounds for the Examiner's rejection, Applicant files herewith a terminal disclaimer with respect to *Janke*.

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome a rejection based on a nonstatutory double patenting ground, provided the conflicting application or patent is shown to be commonly owned with this application. The terminal disclaimer submitted herewith is in compliance with 37 C.F.R. § 1.321(c). The instant application and *Janke* are commonly owned by Cardiac Pacemakers, Inc., duly organized under the laws of Minnesota and having its principal place of business at 4100 Hamline Avenue North, St. Paul, MN 55112. Applicant respectfully requests the withdrawal of the double patenting rejections based on *Janke*, alone or in combination with *Bartig* or *Sommer*, in view of the terminal disclaimer filed herewith.

The filing of the terminal disclaimer in no way manifests an admission by Applicant as to the propriety of the double patenting rejections. See M.P.E.P. § 804.02 citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Applicant reserves the right to traverse the double patenting rejections at a later date.

Accordingly, Applicant respectfully requests that the double patenting rejections of claims 40-43, 46-56, and 59-62 be withdrawn.

II. 35 U.S.C. § 102(e) Rejection Based on *De Lurgio*

Applicant respectfully traverses the rejection of claims 47, 48, and 51 as being anticipated by *De Lurgio*. An anticipation rejection is proper only if each and every element as set forth in the claim is expressly or inherently described in a single prior art reference. M.P.E.P. § 2131. However, *De Lurgio* does not expressly or inherently describe, or even suggest, each and every element set forth in claims 47, 48, and 51.

Independent claim 47 has been amended to include subject matter of claim 52. Now superfluous claim 52 has been canceled. Specifically, amended independent claim 47 recites an implantable lead for implantation by a guidewire on or about the heart including, among other things, “a lead body having distal and proximal ends, the lead body defining a lumen extending from a distal aperture in the distal end of the lead body toward the proximal end of the lead body, . . . and a closable seal disposed at the distal end of the lead body and on an inner surface of the lead body, the closable seal defining a closable seal lumen for receiving the guidewire and includes at least one cusp.”

As noted above, the Office Action rejected claim 52 under 35 U.S.C. § 102(e) as being anticipated by *De Lurgio*. To the extent this rejection relates to amended independent claim 47, Applicant provides the following comments with respect to the 35 U.S.C. § 102(e) rejection.

De Lurgio discloses a pacing lead 32 including a hollow body 34 with a central lumen 36, and a valve 38, 54 having a valve housing 48 that “is affixed to the . . . hollow body [34]” (*De Lurgio*, col. 6, ll. 43-49; col. 8, ll. 1-2; and Figs. 5-8).

However, even if one were to construe that the hollow body 34 of *De Lurgio* corresponds to the claimed lead body defining a lumen, which Applicant does not concede, the hollow body 34 of *De Lurgio* does not include an inner surface on which a closeable seal is disposed. As stated in col. 7, ll. 3-10 of *De Lurgio*:

The valve may be molded to the tip of the pacing lead to form a valve housing, which is continuous with the outer insulation of the pacing lead body. Alternatively, the valve may be housed within a distal metallic ring which also serves as a distal pacing electrode. Or, a separate metallic ring on the distal tip of the pacing lead serves solely as the housing for the valve.

Therefore, the valve 38, 54 of *De Lurgio* is disposed at the tip of the pacing lead 32 and not on an inner surface of the hollow body 34. Accordingly, *De Lurgio* does not disclose or suggest “a closable seal disposed at the distal end of the lead body and on an inner surface of the lead body,” as recited in independent claim 47.

For at least the reasons discussed above, independent claim 47 is patentable over *De Lurgio* because *De Lurgio* fails to teach or suggest every element of the claims. Claims 48 and 51 are also patentable over *De Lurgio* at least due to their dependence from claim 47. In addition, each of claims 48 and 51 recites unique combinations that are neither taught nor suggested by the cited references and, therefore, each is also separately patentable.

III. 35 U.S.C. § 103(a) Rejections Based on *De Lurgio*, Alone or in Combination With *Bartig* or *Sommer*

Applicant respectfully traverses the rejection of claims 47-51, 53, 61, and 62 as being unpatentable under 35 U.S.C. § 103(a). The rejections are improper because the criteria for establishing a *prima facie* case of obviousness has not been met.

Claims 47-51, and 53

Applicant respectfully traverses the rejection of claims 47, 48, and 51 under 35 U.S.C. § 103(a) as being unpatentable over *De Lurgio*.

The Office Action contends that, with regard to the valve of *De Lurgio*, one would “merely substitute one particular suitable sealing arrangement for another to produce predictable results” (Office Action, p. 6, ll. 5-8). However, the Office Action’s contention of what would be obvious to one having ordinary skill in the art does not cure the deficiencies of *De Lurgio* noted above with respect to independent claim 47. Therefore, independent claim 47 is also patentable over *De Lurgio* for at least the same reasons discussed above in connection with the rejection under 35 U.S.C. § 102(e). For at least the same reasons discussed above with regard to independent claim 47, claims 48 and 51 are also patentable over *De Lurgio*. Accordingly, a *prima facie* case of obviousness has not been established with respect to claims 47, 48, and 51 because all the features of the claims have not been considered and given weight.

Applicant also respectfully traverses the rejection of claims 47-51 and 53 under 35 U.S.C. § 103(a) as being unpatentable over *De Lurgio* in view of *Bartig* or *Sommer*.

The Office Action acknowledges that *De Lurgio* does “not explicitly refer to the use of a closeable seal that includes at least one cusp” (Office Action, p. 6, ll. 13-14). The Office Action contends that *Bartig* and *Sommer* discloses this feature (Office Action, p. 6, l. 14 to p. 7, l. 3).

Bartig discloses a sealing disk 50 with an orifice 52, and the disk 50 is disposed in a lumen 17 of a lead 10 (*Bartig*, col. 4, ll. 56-67 and Figs. 10 and 11).

However, *De Lurgio* teaches away from moving the valve 38, 54 into the lumen 36 since the lumen 36 is not large enough to house the valve 38, 54. Furthermore, *De Lurgio* discloses that the valve 38, 54 is “continuous with the outer insulation of the pacing lead body” (*De Lurgio*, col. 7, ll. 3-10). Therefore, modifying the pacing lead of *De Lurgio* to move the valve 38, 54 inside the lumen 36 would render *De Lurgio* unsatisfactory for its intended purpose and change the principle of operation of *De Lurgio*. It has long been held that a proposed modification of the prior art cannot render the prior art “unsatisfactory for its intended purpose” or “change its principle of operation.” M.P.E.P. § 2143.01(V)-(VI). Accordingly, *De Lurgio* and *Bartig* do not disclose or suggest “a closable seal disposed at the distal end of the lead body and on an inner surface of the lead body,” as recited in independent claim 47.

Sommer discloses a seal member 26c that is located within a tip electrode 24c located at a distal tip of the lead body 10 (*Sommer*, col. 2, ll. 51-52; col. 4, ll. 35-38 and 63-66; and Figs. 5 and 6). However, *Sommer* does not disclose or suggest that the seal member 26c is located on an inner surface of the lead body 10. Therefore, *Sommer* does not cure the deficiencies of *De Lurgio* noted above with respect to claim 47, nor was it cited for such disclosure. Accordingly, *Sommer* does not disclose or suggest “a

closable seal disposed at the distal end of the lead body and on an inner surface of the lead body,” as recited in independent claim 47.

Therefore, claim 47 is patentable over *De Lurgio*, *Bartig*, and *Sommer*, and claims 48-51 and 53 are also patentable thereover at least due to their dependence from claim 47. Accordingly, a *prima facie* case of obviousness has not been established with respect to claims 47-51 and 53 because all the features of the claims have not been considered and given weight.

Claims 61 and 62

Applicant respectfully traverses the rejection of claims 61 and 62 under 35 U.S.C. § 103(a) as being unpatentable over *De Lurgio*.

Independent claim 61 recites a method of implanting a lead on or about the heart including, among other things, “disposing a guidewire through a lead, . . . the lead defining a lumen . . . , the lead also including a seal disposed at the distal tip of the lead, the seal defining a seal lumen; [and] after the lead is guided to the desired location, removing the guidewire from the seal lumen whereupon the seal closes to prevent fluids from entering the lumen, the seal closes by having at least a portion of the seal formed from an expandable matrix material which expands when the guidewire is removed from the seal lumen.”

The Office Action acknowledges that *De Lurgio* does “not disclose at least a portion of the seal formed from an expandable matrix material” (Office Action, p. 7, ll. 15-16). On p. 7, l. 20 to p. 8, l. 8, the Office Action contends that:

[I]t would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize an expandable matrix material because the applicants have not disclosed that such material provides an advantage, is used for a particular purpose, or solves a stated problem compared to equally suitable materials such as rubbers and elastomers. One of ordinary skill in the art, furthermore, would have expected the applicants' invention to perform equally well with silastic rubber or siloxane because these materials are biocompatible and elastic. The applicants['] disclosure on page 8 of the present specification that silicone rubber and biocompatible elastomers may be used to form the seal lend further support to the assertion that the invention would work equally well with materials other than expandable matrix materials.

Applicants disagree. The instant application claims priority to U.S. Patent No. 6,240,321 ("the '321 patent"), which is incorporated by reference in the paragraph starting at page 1, line 5. Col. 7, ll. 22-60 of the '321 patent describes nonlimiting examples of the composition of the expandable matrix material and states, among other things, that the expandable matrix material "is adapted to absorb water upon contact with a fluid environment. As water is absorbed, the matrix begins to swell in physical size." Also, col. 11, l. 60 to col. 12, l. 5 of the '321 patent states that, as shown in

Fig. 13:

[A] plug 920 is formed from the expandable matrix material. . . . Upon contact with bodily fluid, the plug 920 expands and seals off the lumen 916. The plug 920 is sized and adapted to expand until it occupies enough of the lumen 916 to seal off harmful entry of fluids. . . . The expanded plug 920 also provides physical support to the exposed electrode 914 so that it is not inadvertently crushed.

Therefore, contrary to the Office Action's assertion, the expandable matrix material provides an advantage, is used for a particular purpose, and solves a stated problem compared to materials such as rubbers and elastomers since the expandable matrix material is capable of, among other things, expanding upon contact with bodily fluid or other fluid. Accordingly, *De Lurgio* does not disclose or suggest that "[a] seal

closes by having at least a portion of the seal formed from an expandable matrix material which expands when the guidewire is removed from the seal lumen,” as recited in independent claim 61.

Therefore, claim 61 is patentable over *De Lurgio*, and claim 62 is also patentable thereover at least due to its dependence from claim 61. Accordingly, a *prima facie* case of obviousness has not been established with respect to claims 61 and 62 because all the features of the claims have not been considered and given weight.

IV. Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance.

The final Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to automatically subscribe to any statement or characterization in the final Office Action.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner and that this application be allowed.

Applicant also submits that the entry of the amendments would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In discussing the specification, claims, and drawings in this Amendment After Final, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or

shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

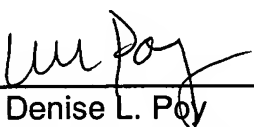
If the Examiner believes a telephone conversation might advance prosecution, the Examiner is cordially invited to call Applicant's undersigned representative at 202-408-4129.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: November 12, 2008

By: 
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Attachment: Terminal Disclaimer